REMARKS

Claims 1-10 remain pending in the present application. Claims 1-10 are currently amended. Applicants would like to thank Examiner Navarro for the courtesy extended to Applicants in the September 14, 2004 Interview.

35 U.S.C. §102(e)

The Office maintains its rejection of claims 1, 2-4, and 6-7 under 35 U.S.C. §102(e) as being anticipated by Szalay *et al.* in U.S. Patent 5,976,796. For 35 U.S.C. §102 to properly apply, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Specifically, the Examiner has argued in the past and argues in the present Office Action the following:

- Szalay *et al.* discloses a method of monitoring gene expression quantitatively and qualitatively in a cell using a gene fusion construct coding for a polypeptide having both luciferase and GFP activities by measuring luciferase and fluorescent activity;
- Szalay *et al.* discloses that luciferase and GFP genes were placed into prokaryotic pGEM-5zf(+) of *E. Coli* through transformation;
- Szalay *et al.* (Figure 5A) discloses photomicrographs of cells transformed by fusion genes using fluorescence microscopy and fluorescence imaging to show GFP activity;
- Szalay *et al.* (Figure 6A) discloses bar graphs of luciferase activity before and after promoter induction of fusion gene constructs of *E. coli*; and
- Szalay *et al.* discloses that GFP and luciferase activities were measured following a 12 hour incubation period using inverted fluorescent microscope for GFP activity and luminometer for luciferase activity. Since measurements were indicative of either luciferase or fluorescence of actively growing cells in culture – according to the Office – the cells measured were either alive at any moment, or are or have been alive when tested.

The claims of the present invention include a limitation –which is not disclosed in the Szalay *et al.* reference– where growth and death rates of micro-organisms are measured based on at least two of the following:

a) the known proportion of luminescence or fluorescence to the amount of cells alive after any said chosen time period,

b) the known proportion of luminescence or fluorescence to the total amount of cells that are or have been alive within any said chosen time period, and

c) the known proportion of luminescence or fluorescence to the total amount of cells that have died within any said chosen time period.

The Szalay *et al.* reference does not disclose that by using (at least) two markers, each correlating with a different member of the group, one can assess the growth rate and death rate of the microorganism. The Office argues that the claim language set forth in 1(c) does not absolutely require that death rate be assessed, because the rate is assessed based on at least two of i), ii), iii), but the Szalay *et al.* reference does not disclose either of at least two of i), ii) or iii) (i.e., i) + ii) or i) + iii) etc.). Unlike the Szalay *et al.* reference, the present invention is able to differentiate between actual growth rate and apparent growth rate – in case the overall live cell count is rising – on the one hand and actual death rate and apparent death rate – in case the overall live cell count is decreasing – in an environment of interest. The present invention unlike the Szalay *et al.* reference, can separately determine how the environment affects the growth rate and the death rate of the microorganism. The Szalay *et al.* reference only discloses the measurement of gene expression in the live cells, but fails to disclose or suggest the measurement of gene expression in other cells. Finally, the Office argues that there is no stipulation regarding a chosen time period in known proportion. We respectfully disagree. However, the limitations of claim 1(c) refers to any chosen time period. The present invention allows for measurement at any time period, which is of known proportion.

The Szalay *et al.* reference therefore lacks a disclosure of at least one element of the invention claimed here and cannot form the basis of an anticipation rejection. Applicants therefore request withdrawal of the rejection of claims 1-10 over Szalay *et al.*

35 U.S.C. §112, second paragraph

The Office rejected claims 1-10 under 35 U.S.C. §112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Office argues that the recitation of "which method is characterized in that" and "characterized in that" is unclear. The claims have been amended to recite "wherein" instead of "...which method is characterized in that" and "characterized in that."

The Office also asserts that the claims are unclear because they appear to lack positive active method steps. Step (b) of Claim 1 has been amended by replacing "is incubated" with "incubating" and replacing "is detected" with "detecting." Step 1(c) of Claim 1 has been amended by replacing "is assessed" with "assessing." Step 1(c) of Claim 1 has also been amended to insert "measuring" before "at least."

In view of the amendments to the claims, it is submitted that the claims are definite. Withdrawal of this rejection is requested.

Claim Objections

The Office objected to claim 1 and claims 3-10 because of informalities. Claim 1 has been amended to replace "...of interest by" with "...of interest comprising." In view of the amendment to claim 1, withdrawal of this rejection is requested.

In view of the above amendments and remarks, in conjunction with the remarks made in the previous responses, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the prior art. Reconsideration of the instant application and early notice of

allowance are requested. The Office is invited to telephone the undersigned to expedite allowance of this application.

Respectfully submitted,
ROTHWELL, FIGG, ERNST & MANBECK, p.c.

By Leigh Z. Callander by Jeffrey L. Ihnen Reg. No. 28,957

Leigh Z. Callander
Registration No. 55,035
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
Telephone No.: (202) 783-6040
Facsimile No.: (202) 783-6031

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